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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	10/665,079		
Filing Date	09/16/03		
First Named Inventor	Bacopoulos		
Group Art Unit	1614		
Examiner Name	Not Yet Assigned		
Attorney Docket Number	24852-501 CIP5		

				U.S. PATENT DOCUMENTS			
Exam Initials	Cite No.	U.S. Patent Document No.	Issue Date Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date	
	A1°	5,055,608	10/08/91	Marks et al.	560	169	06/30/89
	A2*	5,175,191	12/29/92	Marks et al.	514	575	05/14/90
	A3*	5,369,108	11/29/94	Breslow et al.	514	266	10/04/91
	A4*	5.608,108	03/04/97	Marks et al.	562	621	04/17/95
	A5*	5,700,811	12/23/97	Breslow et al.	514	314	05/19/94
	A6*	5.773,474	06/30/98	Breslow et al.	514	616	06/07/95
	A7*	5,932,616	08/13/99	Breslow et al.	514	532	04/04/94
	A8*	6.087,367	06/11/00	Breslow et al.	514	266	05/18/99
	A9*	6,511,990	01/28/03	Breslow et al.	514	314	08/24/00

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j	B1*	wo	98/40080	Beacon Laboratories, L.L.C.	September 17, 1998	X	
11	B2*	wo	00/21979	Fujisawa Pharmaceutical Co., LTD	April 20, 2000	X	
i	B3*	wo	00/71703	Methylgene, Inc.	November 30, 2000	X	
1	B4*	wo	01/18171	Sloan-Kettering Institute for Cancer Research & The Trustees of Columbia University in the City of New York	March 15, 2001	х	
	B5*	wo	01/38322	Methylgene, Inc.	May 31, 2001	X	
<del>_'</del>	B6*	wo	01/70675	Methylgene, Inc.	September 27, 2001	Х	
1	B7*	wo	02/22577	Novartis-Erfindungen Verwaltungsgesellschaft M.B.H.	March 21, 2002	х	
<del></del>	B8*	wo	02/30879	Prolifix Limited	April 18, 2002	X	
	B9*	wo	02/46144	F. Hoffmann-La Roche AG	June 13, 2002	Х	

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,	C2*	Archer et al. (1998). Proc. Natl. Acad. Sci. USA 95: 6791-6796.				
1	C3*	Bhalla et al. (2002). "Co-treatment With The Histone Deacetylase Inhibitor Suberoylanilide Hydroxamic Acid (SAHA) Enhances the Cytotoxic Effects of Gleevec and Arsenic Trioxide (AT) Against Bcr-Abl Positive Human Leukemia Cells." <i>American Society of Hematology</i> , 44 <sup>th</sup> Meeting of the American Society of Hematology, Abstract 4611.				
ì	C4*	Butler et al. (2000). Cancer Res. 60: 5165-5170.				
1	C5*	Butler et al. (2001). Clincal Cancer Res. 7: 962-970.				
•	C6*	Butler et al. (2002). Proc. Natl. Acad. Sci. USA 99: 11700-11705.				
1	C7*	Coffey et al. (2000). Medical and Pediatric Oncology 35: 577-581.				

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		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
1	C8*	Coffey et al. (2001). Cancer Res. 61: 3591-3594.
1	C9.	Cohen et al. (1999). Anticancer Res. 19: 4999-5006.
1	C10*	Cohen et al. (2002). Anticancer Res. 22: 1497-1504.
t	C11'	Curtin (2002). Exp. Opin. Ther. Patents 12: 1375-1384.
1	C12*	Dressel (2000). Anticancer Res. 20: 1017-1022.
ı	C13*	Fei et al. (2002). "Co-treatment With the Histone Deacetylase Inhibitor Suberoylanilide Hydroxamic Acid (SAHA) Enhances Apo-2L/TRAIL-induced Death Inducing Signaling Complex and Apoptosis of Human Acute Lymphoid Leukemia Cells." American Society of Hematology, 44 <sup>th</sup> Meeting of the American Society of Hematology Abstract No. 4602.
ı	C14*	Feinman et al. (2002). "The Histone Deacetylase Inhibitor, Suberoylanilide Hydroxamic Acid, Induces Apoptosis of Multiple Myeloma Cells." <i>American Society of Hematology</i> , 44 <sup>th</sup> Meeting of the American Society of Hematology, Abstract No. <b>3195</b> .
	C15*	Finnin et al. (1999). <i>Nature</i> 401: 188-193.
•	C16*	Furamai et al. (2001). Proc. Natl. Sci. USA 98: 87-92.
1	C17*	Grunstein (1997). Nature 389: 349-352.
j	C18*	He et al. (2001). J. Clin. Investigation 108: 1321-1330.
<del></del>	C19*	Hockly et al. (2003). Proc. Natl. Acad. Sci. USA 100: 2041-2046.
,	C20*	Kelly et al. (2001). "Suberoylanilide Hydroxamic Acid (SAHA), a Histone Deacetylase Inhibitor: Biologic Activity Without Toxicity." <i>American Society of Clinical Oncology</i> , Abstract No. 344.
,	C21*	Kelly et al. (2002). "Histone deacetylase inhibitor, suberoylanilide hydroxamic acid (SAHA), orally administered has good bioavailability and biologic activity." <i>American Society of Clinical Oncology</i> , 38 <sup>th</sup> Annual Meeting of the American Society of Clinical Oncology, November 7-10, 2002, Abstract No. 1831.
!	C22*	Kelly et al. (2002). "A phase I clinical trial of an oral formulation of the histone deacetylase inhibitor suberoylanilide hydroxamic acid (SAHA)." European J. Cancer 38(Suppl. 7): 88, Abstract No. 286.
•	C23*	Kim et al. (1999). Oncogene <u>18</u> : 2461-2470.
1	C24*	Kohge et al. (1998). Biochem. Pharmacol. <u>56</u> : 1359-1364.
1	C25*	Komatsu et al. (2001). Cancer Res. 61: 4459-4466.
1	C26*	Kouraklis and Theocharis (2002). Curr. Med. Chem.Anti-Cancer Agents 2: 477-484.
•	C27*	Lee et al. (2001). Cancer Res. 61: 931-934.
•	C28*	Lin et al. (1998). Nature 391: 811-814.
١.	C29*	Mai et al. (2001). OPPI Briefs <u>33</u> : 391-394
	C30*	Marks et al. (2000). J. of the Natl. Cancer Institute 92: 1210-1215.
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1	C32*	Marks et al. (2001). Curr. Opin. In Oncology 13: 477-483.
	C33*	Marks et al. (2001). Nature Reviews 1: 194-202.
1	C34*	Miller et al. (2003). J Med Chem. 46: 5097-5116.
	C35*	Munster et al. (2001). Cancer Res. 61: 8492-8497.
	C36*	O'Connor et al. (2002). "Clinical experience of the histone deacetylase inhibitor suberoylanalide hydroxamic acid (SAHA) in heavily pre-treated patients with aggressive non-hodgkin's lymphoma (NHLO and hodgkin's disease (HD))." American Society of Clinical Oncology, December 6-10, 2002, Abstract No. 4742.
:	C37*	Qui et al. (2000). Mol. Biol. Cell 11: 2069-2083.
1	C38*	Richon et al. (1996). Proc. Natl. Acad. Sci. USA 93: 5705-5708.
i	C39,	Richon et al. (1998). Proc. Natl. Acad. Sci. USA 95: 3003-3007.
<del></del>	C40*	Richon et al. (2000). Proc. Natl. Acad. Sci. USA 97: 10014-10019.
<del>.</del>	C41*	Richon and O'Brien (2002). Clinical Cancer Res. 8: 662-664.
ľ	C42*	Saito et al. (1999). Proc. Natl. Acad. Sci. USA 96: 4592-4597.
<del>-  </del>	C43*	Sgouros et al. (2002). "Synergistic Interaction of Suberoylanilide Hydroxamic Acid (SAHA) and

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	OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS					
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.				
		Radiation in Human Prostate Tumor Spheroids." <i>American Society of Clinical Oncology</i> , Abstract No. 105.				
1	C44*	Stowell et al. (1995). J. Med. Chem. 38: 1411-1413.				
Ī	C45*	Su et al. (2000). Cancer Res. 60: 3137-3142.				
1	C46*	Suzuki et al. (1999). J. Med. Chem. 42: 3001-3003.				
1	C47*	Van Lint et al. (1996). Gene Expression <u>5</u> : 245-253.				
1	C48*	Vrana et al. (1999). Oncogene 18: 7016-7025.				
:	C49*	Webb et al. (1999). J. Biol. Chem. 274: 14280-14287.				
i	C50*	Yoshida et al. (1990). J. Biol. Chem. 265: 17174-17179.				
ī	C51*	Yoshida et al. (1995). BioEssays 17: 423-430.				
i	C52*	Zhou et al. (1999). Gene 233: 13-19.				
i i	C53*	Zhou et al. (2000). Proc. Natl. Acad. Sci. USA 97: 1056-1061.				
	C54*	Zhou et al. (2000). Proc. Natl. Acad. Sci. USA 97: 14329-14333.				
<del>-</del>	C55*	Zhou et al. (2001). Proc. Natl. Acad. Sci. USA 98: 10572-10577.				

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. 10/379,149, filed March 4, 2003, and relied upon for an earlier filing date under 35 U.S.C. §120 (continuation, continuation-in-part, and divisional applications).

Examiner Signature	Date Considered	

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Application Number	10/379,149
Filing Date	March 4, 2003
First Named Inventor	Victoria M. Richon and Judy H. Chiao
Group Art Unit	1614
Examiner Name	Not Yet Assigned
Attorney Docket Number	24852-501
	Filing Date First Named Inventor Group Art Unit Examiner Name

				U.S. PATENT DOCUMENTS			
Exam Initials	Cite No.	U.S. Patent Document No.	Issue Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date
	Ã1	5,055,608	10/08/91	Marks et al.	560	169	06/30/89
	A2	5,175,191	12/29/92	Marks et al.	514	575	05/14/90
	A3	5,369,108	11/29/94	Breslow et al.	514	266	10/04/91
	A4	5,608,108	03/04/97	Marks et al.	562	621	04/17/95
	A5	5,700,811	12/23/97	Breslow et al.	514	314	05/19/94
	A6	5,773,474	06/30/98	Bresloe et al.	514	616	06/07/95
	A7	5,932,616	08/13/99	Breslow et al.	514	532	04/04/94
	AB	6.087.367	06/11/00	Breslow et al.	514	266	05/18/99
	A9	6,511,990	01/28/03	Breslow et al.	514	314	08/24/00

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Exam Initials	Cite No.	Foreig Office	n Patent Document Number	Name of Patentee(s) or Applicant(s)	Date of Publication	Trans Yes	lation No
	B1	wo	98/40080	Beacon Laboratories, L.L.C.	September 17, 1998	Х	
	B2	wo	00/21979	Fujisawa Pharmaceutical Co., LTD	April 20, 2000	X	
	B3	wo	00/71703	Methylgene, Inc.	November 30, 2000	Χ	
	B4	wo	01/18171	Sloan-Kettering Institute for Cancer Research & The Trustees of Columbia University in the City of New York	March 15, 2001	х	
	B5	wo	01/38322	Methylgene, Inc.	May 31, 2001	Х	<u>L_</u>
	B6	wo	01/70675	Methylgene, Inc.	September 27, 2001	Х	L
•	B7	wo	02/22577	Novartis-Erfindungen Verwaltungsgesellschaft M.B.H.	March 21, 2002	х	
	B8	wo	02/30879	Prolifix Limited	April 18, 2002	X	
	B9	wo	02/46144	F. Hoffmann-La Roche AG	June 13, 2002	Х	

	OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS					
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.				
	C1	Andrews et al. (2000). Intl. J. Parasitol. 30: 761-768.				
	C2	Archer et al. (1998). Proc. Natl. Acad. Sci. USA 95: 6791-6796.				
	СЗ	Bhalla et al. (2002). "Co-treatment With The Histone Deacetylase Inhibitor Suberoylanilide Hydroxamic Acid (SAHA) Enhances the Cytotoxic Effects of Gleevec and Arsenic Trioxide (AT) Against Bcr-Abl Positive Human Leukemia Cells." <i>American Society of Hematology</i> , 44 <sup>th</sup> Meeting of the American Society of Hematology, Abstract 4611.				
	C4	Butler et al. (2000). Cancer Res. 60: 5165-5170.				
	C5	Butler et al. (2001). Clincal Cancer Res. 7: 962-970.				
	C6	Butler et al. (2002). Proc. Natl. Acad. Sci. USA 99: 11700-11705.				
	C7	Coffey et al. (2000). Medical and Pediatric Oncology 35: 577-581.				

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FEB 2 6 2004	5		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS
	xam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
A TRADE		C8	Coffey et al. (2001). Cancer Res. 61: 3591-3594.
		C9	Cohen et al. (1999). Anticancer Res. 19: 4999-5006.
		C10	Cohen et al. (2002). Anticancer Res. 22: 1497-1504.
		C11	Curtin (2002). Exp. Opin. Ther. Patents 12: 1375-1384.
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		C13	Fei et al. (2002). "Co-treatment With the Histone Deacetylase Inhibitor Suberoylanilide Hydroxamic Acid (SAHA) Enhances Apo-2L/TRAIL-induced Death Inducing Signaling Complex and Apoptosis of Human Acute Lymphoid Leukemia Cells." <i>American Society of Hematology</i> , 44 <sup>th</sup> Meeting of the American Society of Hematology Abstract No. 4602.
		C14	Feinman et al. (2002). "The Histone Deacetylase Inhibitor, Suberoylanilide Hydroxamic Acid, Induces Apoptosis of Multiple Myeloma Cells." <i>American Society of Hematology</i> , 44 <sup>th</sup> Meeting of the American Society of Hematology, Abstract No. 3195.
		C15	Finnin et al. (1999). <i>Nature</i> <u>401</u> : 188-193.
		C16	Furamai et al. (2001). Proc. Natl. Sci. USA 98: 87-92.
Ì		C17	Grunstein (1997). Nature 389: 349-352.
		C18	He et al. (2001). J. Clin. Investigation 108: 1321-1330.
Ì		C19	Hockly et al. (2003). Proc. Natl. Acad. Sci. USA 100: 2041-2046.
		C20	Kelly et al. (2001). "Suberoylanilide Hydroxamic Acid (SAHA), a Histone Deacetylase Inhibitor: Biologic Activity Without Toxicity." <i>American Society of Clinical Oncology,</i> Abstract No. 344.
		C21	Kelly et al. (2002). "Histone deacetylase inhibitor, suberoylanilide hydroxamic acid (SAHA), orally administered has good bioavailability and biologic activity." <i>American Society of Clinical Oncology</i> , 38 <sup>th</sup> Annual Meeting of the American Society of Clinical Oncology, November 7-10, 2002, Abstract No. 1831.
		C22	Kelly et al. (2002). "A phase I clinical trial of an oral formulation of the histone deacetylase inhibitor suberoylanilide hydroxamic acid (SAHA)." European J. Cancer 38(Suppl. 7): 88, Abstract No. 286.
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Ì		C31	Marks et al. (2001). Clinical Cancer Res. 7: 759-760.
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Ì		C37	Qui et al. (2000). Mol. Biol. Cell 11: 2069-2083.
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•	-,	C40	Richon et al. (2000). <i>Proc. Natl. Acad. Sci. USA</i> <u>97</u> : 10014-10019.
Į.		_	Richon and O'Brien (2002). Clinical Cancer Res. 8: 662-664.
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		C41 C42	Saito et al. (1999). <i>Proc. Natl. Acad. Sci. USA</i> <u>96</u> : 4592-4597.

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જે		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS
Ekam Chitlais	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
		Radiation in Human Prostate Tumor Spheroids." <i>American Society of Clinical Oncology</i> , Abstract No. <b>105</b> .
	C44	Stowell et al. (1995). J. Med. Chem. 38: 1411-1413.
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	C49	Webb et al. (1999). J. Biol. Chem. 274: 14280-14287.
	C50	Yoshida et al. (1990). J. Biol. Chem. 265: 17174-17179.
	C51	Yoshida et al. (1995). BioEssays 17: 423-430.
	C52	Zhou et al. (1999). Gene 233: 13-19.
	C53	Zhou et al. (2000). Proc. Natl. Acad. Sci. USA 97: 1056-1061.
	C54	Zhou et al. (2000). Proc. Natl. Acad. Sci. USA 97: 14329-14333.
	C55	Zhou et al. (2001). Proc. Natl. Acad. Sci. USA 98: 10572-10577.

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. \_\_\_\_\_\_, filed \_\_\_\_\_\_, and relied upon for an earlier filing date under 35 U.S.C. §120 (continuation, continuation-in-part, and divisional applications).

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